



04.14.05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: ABDEL-MONEM, et al.)
) APPEAL NO. _____
SERIAL NO: 10/712,422)
)
FOR: METAL COMPLEXES OF ALPHA)
)
AMINO DICARBOXYLIC ACIDS)
) BRIEF ON APPEAL
)
)
FILED: November 13, 2003)
)
GROUP ART UNIT: 1625)

To the Commissioner of Patents and Trademarks
Mail Stop PATENT APPEAL,
P. O. Box 1450,
Alexandria, VA 22313-1450

Dear Sirs:

Please enter the following Brief on Appeal into the record.

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that this document and the documents referred to as enclosed therein are being deposited with the U. S. Postal Service in an envelope as "Express Mail Post Office to Addressee" addressed to: Commissioner of Patents, Mail Stop PATENT APPEAL, P. O. Box 1450, Alexandria, VA 22313-1450, prior to 5:00 p.m. on 13 day of April, 2005.

Betty J. Albritton
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TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	REAL PARTY OF INTEREST	1
III.	RELATED APPEALS AND INTERFERENCES.....	1
IV.	STATUS OF CLAIMS	1
V.	STATUS OF AMENDMENTS	2
VI.	SUMMARY OF CLAIMED SUBJECT MATTER	2
VII.	GROUNDHS OF REJECTION TO BE REVIEWED ON APPEAL.....	2
VIII.	ARGUMENT	3
A.	Claims 1 and 2 are Not Indefinite Under 35 U.S.C. § 112, Second Paragraph.....	2
1.	The Functional Phrase Here Selected is Time Honored and Case Law Approved.....	3
B.	Claims 1 and 2 are Not Obvious Over Kirschner	4
1.	Scope and Contents of Prior Art	5
2.	Differences Between Prior Art and the Claims at Issue.....	6
3.	Level of Ordinary Skill in the Pertinent Art.....	6
IX.	CONCLUSION.....	8

APPENDIX - CLAIMS

REQUEST FOR ORAL HEARING



I. INTRODUCTION

This is an appeal of the Final Rejection dated January 27, 2005, finally rejecting claims 1 and 2. The appealed claims are set forth in an attached Appendix.

II. REAL PARTY OF INTEREST

The real party of interest in the present appeal is the assignee, Zinpro Corporation, a Minnesota corporation of Eden Prairie, Minnesota, by an assignment from the co-inventors recorded in the parent application of which this is a divisional, U. S. Patent Application Serial No. 10/272,382 recorded on February 24, 2003 at Reel/Frame 013778/0042.

III. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences at the time of this filing. It is, however, expected that the parent case relating to the compounds as opposed to this method of use case (parent case Serial No. 10/272,382 filed 10/16/2002) may also be pending on appeal at the same time as this case, unless prosecution is resolved short of appeal.

IV. STATUS OF CLAIMS

Claims 1 and 2 were originally submitted as claims 12 and 13 in the parent application, U. S. Serial No. 10/272,382, but were divided out in a response to a restriction requirement in the parent application. This Divisional of U. S. Serial No. 10/272,382 was filed November 13, 2003 in response to a restriction requirement, and was assigned Serial No. 10/712,422. Claims 1 and 2 were amended October 26, 2004 in response to a July 22, 2004 Office Action. Final rejection of those amended claims was issued January 27, 2005.

Following the final rejection of January 27, 2005, Appellant filed a Notice of Appeal dated April 11, 2005. The claims here appealed are claims 1 and 2.

V. STATUS OF AMENDMENTS

No Amendments were filed following the Examiner's Final Rejection dated January 27, 2005. A Notice of Appeal was timely filed on April 11, 2005.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 sets forth a method of nutritional supplementation of animals by feeding to an animal a small but nutritional supplementing effective amount of a 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino acid.

Claim 2 depends from claim 1 and provides that the animal is a domesticated livestock or poultry animal.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claim 1 stands rejected under 35 U.S.C. § 112 for failing to point out and distinctly claim, second paragraph of 112, with the Examiner rejecting to the phrase "small but nutritional supplementation effective amount", apparently on the basis that the Examiner wishes to have precise number ranges in the claim.

B. Claims 1 and 2 have been rejected as being unpatentable for a reason of obviousness under 35 U.S.C. § 103(a) over Kirschner et al., U. S. Patent No. 6,352,713.

VIII. ARGUMENT

A. Claims 1 and 2 are Not Indefinite Under 35 U.S.C. § 112, Second Paragraph

The Examiner's final rejection simply repeats the 35 U.S.C. § 112, second paragraph, objection of the first Office Action dated July 22, 2004. There the Examiner argued that the phrase "a small but nutritional supplementation effective amount" is vague and indefinite

because the terms "small" and "effective amount" do not state how much the effective amount can be (7/22/2004 Office Action, P2).

1. The Functional Phrase Here Selected is Time Honored and Case Law Approved

It has long been held, even by the predecessor of the Federal Circuit, the Court of Customs and Patent Appeals that phraseology such as "small" or "an effective amount" are not indefinite where the amount as such is not critical, even if the functional words are at the point of novelty (see *In re Halleck*, 164 U.S.P.Q. 647) (CCPA 1970). Similarly, in *In re Frederickson and Nelson*, 102 U.S.P.Q. 35 (CCPA 1954), the court said that a small but effective amount is an adequate description under paragraph 2 of 35 U.S.C. § 112 where the function of the active is stated. Here the function of the active is stated, i.e., a nutritional supplementation effective amount. To the same effect is a more recent case of *In re Watson*, 186 U.S.P.Q. 111 (CCPA 1975) pointing out that there is nothing indefinite about saying an effective amount if the stated function to be achieved is recited in the claim. Here the stated function is recited in the claim, i.e., a nutritional supplementation effective amount. Other cases could be recited but the point is made. The Examiner's rejection is erroneous. It should be reversed since the claim itself used a time honored and approved format, and since the stated function is in fact recited in the claim, there is nothing indefinite.

Finally, it is pointed out that the claims are to be interpreted in light of the specification and the specification itself provides not only the functional guidelines recited in

the claims but also specific ranges (see Example 9, Table 2 for recommended feeding amounts at Specification, page 17).

B. Claims 1 and 2 are Not Obvious Over Kirschner

Claim 1 as appealed requires a feeding of a specific compound, i.e., a 1:1 neutral complex of an essential trace element and a dicarboxylic α -amino acid. Important to the complex is that it is a neutral complex; and it is also a 1:1 complex, i.e., the amino acid legand is selected to serve a dual role, it is the bidentate legand that forms the 1:1 complex with the metal ion and it is the counter ion to balance the charge of the cationic charge of the trace element metal. These novel 1:1 complexes of di α -amino carboxylic acid have excellent physical properties making them highly useful for nutritional supplementation and for providing bio available trace minerals, because unlike other 1:1 complexes, the novel complexes here have excellent physical properties so they can be shipped, stored, and added to feed in carrier-free form (Specification page 8, lines 1-6). Nothing in the art predicts these physical parameters such that the compounds become useful in the nutritional process.

It is the theory of the Examiner's obviousness rejection that Kirschner teaches a method for providing prenatal nutritional supplementation containing ferrous glutamate (see column 12, lines 9-10) to pregnant women in dosages of from 10 mg to 200 mg (see column 12, lines 14-15), and further says that one of the intended usages of this composition can be in animal feed (see column 8, lines 65-66). The Examiner argues therefore it would have been obvious to the skilled artisan to adjust the effective amount of the iron depending upon the weight of the animal by routine experimentation and that there is a teaching in the

reference of equivalence between human use and animal use (see 7/22/2004 Office Action, p.5).

The problem with the Examiner's obviousness rejection are several fold. First it is ambiguous whether the reference even teaches 1:1 neutral metal dicarboxylic acid complexes. Second, at best the reference is indefinite and might teach one of such compounds amongst hundreds disclosed, but this simply does not make the methodology of claim 1 obvious, since it is a new use, and new uses are patentable 35 U.S.C. § 100(b). Third, the brief teaching in Kirschner would not in a *prima facie* obvious way suggest the nutritional feed supplementation method of Applicant.

Kirschner fails to make the invention defined in method claims 1 and 2 obvious for at least the following reasons.

1. Scope and Contents of Prior Art

The invention described in U.S. 6,352,713 B1 relates specifically to "novel chewable prenatal nutritional supplements which contain vitamin C, as well as novel methods for providing optimal vitamin C supplementation to pregnant women." The examples and claims of U. S. 6,352,713 B1 relate to mixtures of selected ingredients that incorporated into nutritional supplements that "were prepared using conventional methods and materials known in the pharmaceutical art" (column 17, lines 13-14). The Kirschner invention does not describe the preparation or properties of any of these ingredients in detail. The scope of the present claims relates to specific complexes of trace metals and enhanced bioavailability to serve as feed ingredients. In the present application, the structure of products is provided,

identity is confirmed by FTIR and HPLC, and their homogeneity demonstrated by HPLC.

The elemental analysis of products is meaningful and confirms purity. One is left to guesswork in Kirschner.

2. Differences Between Prior Art and the Claims at Issue

U.S. 6,352,713 B1 claims "a substantially non-acidic chewable prenatal nutritional tablet composition" containing a variety of ingredients commonly used in human nutrition. For each nutrient, Kirschner lists possible sources of the nutrient without fully describing the nature and properties of the source. Beginning with line 5, column 12 the inventors list 14 commercially available sources of iron. One of these is ferrous glutamate. However, Kirschner also states on line 12 "Preferably, the iron compound is ferrous fumarate, carbonyl iron or mixtures thereof." This indicates that ferrous glutamate is not a preferred source of iron and would not inspire others to pursue these compounds for further development. It should be emphasized that the exact nature of ferrous glutamate is not specified by Kirschner. A substance containing iron in the ferrous state and glutamic acid could be one of three different chemical entities, or a mixture of two or all three. Indeed, the substance that was used in the past as a source of iron and sold as Ferrous Glutamate is of indefinite structure and appears to be a mixture of more than one chemical entity.

3. Level of Ordinary Skill in the Pertinent Art

The purpose of the present application is to invent and use for nutrition 1:1 complexes of trace elements that will have commercial utility by being superior to currently available products for trace element feed supplements. This required the identification of

desirable chemical, physical and nutritional properties. Based on these three requirements, potential complexes were designed and then prepared. The physical and chemical properties of these complexes were determined and the complexes that possessed the desired properties were selected. The bioavailability of selected complexes was determined in animal studies (see Example 9). Complexes shown to have superior bioavailability in animal studies were further evaluated for improving the performance of livestock. Kirschner as evident by its classification (cl 124/441) relates to humans. It should be apparent that nothing that has been disclosed in U.S. 6,352,713 B1 would make any part of this application's problem or its resolution *prima facie* obvious. The Examiner's assertion that the inclusion of ferrous glutamate in a list of examples of iron compounds provides guidance to the invention described in this application is unreasonable. Kirschner lists more than 100 compounds including vitamins, minerals and antacids. All of these compounds are commercially available well-known compounds, including ferrous glutamate that are or have been used as nutritional supplements in humans. Some of the substances listed in U.S. 6,352,713 B1 including ferrous glutamate are of indefinite composition (possibly defining three compounds) and their efficacy for the present method has not been demonstrated. Therefore, Kirschner does not provide any new or unique knowledge that make claims 1 and 2 obvious.

The novel aspects of the appealed claims include the methodology and the invention of complexes of precise chemical structure, describing methods for their preparation of high yields, providing evidence of their chemical, physical, and biological properties, documenting their physical properties and ability to use them to improve the performance of livestock, and

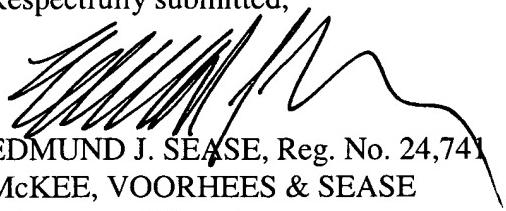
demonstrating their commercial utility in the method. None of this is *prima facie* suggested by Kirschner. Thus, careful examination of "the differences between the subject matter sought to be patented and the prior art" would clearly indicate that "the subject matter as a whole" would have not been obvious from U.S. 6,352,713 B1 at the time of the invention.

IX. CONCLUSION

The Examiner urges that Kirschner is relevant to the claimed invention. Given the loosest definition of relevance, it may be relevant, but it does not establish a *prima facie* case of obviousness for all the reasons earlier recited. Moreover, case law directly contradicts the Examiner's 35 U.S.C. § 112, second paragraph objection. The decision of the Examiner on both 35 U.S.C. § 112 and on obviousness should be reversed and the case allowed.

Enclosed herein please find the Appeal Brief and the required fee of \$250 for a small entity. Also enclosed is a Request for Oral Hearing and the required fee of \$500. If this amount is not correct, please consider this a request to debit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,



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APPENDIX

Claim 1. A method of nutritional supplementation of animals, comprising:
feeding a small but nutritional supplementation effective amount,
a 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino acid to an
animal.

Claim 2. The method of claim 1 wherein the animal is a domesticated livestock or
poultry animal.



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GROUP: 1625)
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EXAMINER: OH, Taylor Victor)

APPEAL NO. _____

REQUEST FOR ORAL HEARING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

COMES NOW the Applicant and requests an oral hearing on the above-identified appeal. This request is being filed simultaneously with the \$500.00 oral hearing fee.

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If any additional fees are due, please charge Deposit Account No. 26-0084. (One additional copy of this Notice is enclosed herewith).

Respectfully submitted,



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